K130253

JUL 15 2013

510(k) Summary
COULTER TQ Prep Sample Preparation and COULTER PrepPlus 2 Workstations

1.0 **Submitted By:**

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2.0 **Date Submitted:**

January 28, 2013

3.0 **Device Name/Trade Name – Classification**

COULTER TQ Prep Sample Preparation Workstation - Pipetting and Diluting System for Clinical Use (21 CFR § 862.2750); product code: PER

COULTER PrepPlus 2 Sample Preparation Workstation – Pipetting and Diluting System for Clinical Use (21 CFR § 862.2750): product code: PER

4.0 **Predicate Devices:**

Candidate	Predicate	Manufacturer	510(k) Number
TQ-Prep	Q-Prep	Beckman Coulter, Inc.	K874188
PrepPlus 2	Manual Pipette	Various	Not applicable

5.0 **Description:**

The COULTER TQ-Prep Workstation is used with the COULTER ImmunoPrep Reagent System to prepare leukocytes from whole blood for measurement on flow cytometers. The COULTER PrepPlus 2 is a microprocessor-controlled pipetting and diluting system, designed for automating sample preparation or assay methods. It is capable of aspirating and dispensing liquid samples.

6.0 **Intended Use:**

PrepPlus 2
Intended Use:
The COULTER PrepPlus 2, when used in combinations with the COULTER TQ-Prep Workstation, is intended to prepare human whole blood for In Vitro Diagnostic (IVD) Use with cleared Beckman Coulter IVD applications on cleared Beckman Coulter flow cytometers (see list below).

Indications for Use:
Pipetting blood, cleared Beckman Coulter IVD reagents and Flow-Count Fluorospheres to prepare samples for flow cytometric analysis. Use of the PrepPlus 2 with cleared Beckman Coulter flow cytometers is described in each application Instructions for Use.

For In Vitro Diagnostic Use Only

TQPrep
Intended Use:

The COULTER TQ-Prep Workstation is intended to prepare leukocytes from whole blood for In Vitro Diagnostic (IVD) Use when used with the COULTER ImmunoPrep Reagent System and cleared Beckman Coulter IVD applications on cleared Beckman Coulter flow cytometers (see list below).

Indication for Use:
Pipetting of ImmunoPrep Reagent System (lyse, stabilizer, and fixative reagents) to samples prepared either manually or with the COULTER PrepPlus 2 sample preparation device to achieve lysis of whole blood samples. Use of COULTER TQ-Prep with cleared Beckman Coulter flow cytometers is described in each application's Instructions for Use.

For In Vitro Diagnostic Use Only

IVD Applications

The following cleared Beckman Coulter IVD applications can be used with the TQ-Prep and PrepPlus2 Workstations on cleared Beckman Coulter flow cytometers as described in each application's Instructions for Use.

- CYTO-STAT tetraCHROME CD45-FITC/CD4-RD1/ CD8-ECD/CD3-PC5
- CYTO-STAT tetraCHROME CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5
- CYTO-STAT triCHROME CD45-FITC/CD4-RD1/CD3-PC5
- CYTO-STAT triCHROME CD45-FITC/CD8-RD1/CD3-PC5
- CYTO-STAT triCHROME CD45-FITC/CD56-RD1/CD3-PC5
- CYTO-STAT triCHROME CD45-FITC/CD19-RD1/CD3-PC5
- CYTO-STAT triCHROME CD8-FITC/CD4-RD1/CD3-PC5
- CYTO-STAT / COULTER CLONE CD3(IgG1)-FITC/T4-RD1
- CYTO-STAT / COULTER CLONE CD3(IgG1)-FITC/T8-RD1
- CYTO-STAT CD3-FITC/CD56-RD1
- CYTO-STAT / COULTER CLONE T4-RD1/T8-FITC
- CYTO-STAT / COULTER CLONE T8-FITC (CD8- FITC)
- CYTO-STAT / COULTER CLONE T8-RD1 (CD8-RD1)
- CYTO-STAT / COULTER CLONE T4-FITC (CD4- FITC)
- CYTO-STAT / COULTER CLONE T4-RD1 (CD4-RD1)
- CYTO-STAT / COULTER CLONE CD3(IgG1)-FITC
- CYTO-STAT / COULTER CLONE CD3(IgG1)-RD1

7.0 Comparison to Predicates:

Similarities and Differences between Q-Prep and TQ-Prep Workstations

Attribute	Q-Prep (Predicate)	TQ-Prep
Intended Use	Q-PREP is used to prepare leukocytes for immunofluorescence measurements on optical flow cytometers.	Intended Use: The COULTER TQ-Prep Workstation is intended to prepare leukocytes from whole blood for In Vitro Diagnostic (IVD) Use when used with the COULTER ImmunoPrep Reagent System and cleared Beckman Coulter IVD applications on cleared Beckman Coulter flow cytometers (see list below). Indication for Use: Pipetting of ImmunoPrep Reagent System (lyse, stabilizer, and fixative reagents) to samples prepared either manually or with the COULTER PrepPlus 2 sample preparation device to achieve lysis of whole blood samples. Use of COULTER TQ-Prep with cleared Beckman Coulter flow cytometers is described in each application's Instructions for Use. For In Vitro Diagnostic Use Only **IVD Applications** The following cleared Beckman Coulter IVD applications can be used with the TQ-Prep and

Attribute	Q-Prep (Predicate)	TQ-Prep
		PrepPlus2 Workstations on cleared Beckman Coulter flow cytometers as described in each application's Instructions for Use. • CYTO-STAT tetraCHROME CD45-FITC/CD4-RD1/ CD8-ECD/CD3-PC5 • CYTO-STAT tetraCHROME CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 • CYTO-STAT triCHROME CD45-FITC/CD4-RD1/CD3-PC5 • CYTO-STAT triCHROME CD45-FITC/CD8-RD1/CD3-PC5 • CYTO-STAT triCHROME CD45-FITC/CD56-RD1/CD3-PC5 • CYTO-STAT triCHROME CD45-FITC/CD19-RD1/CD3-PC5 • CYTO-STAT triCHROME CD8-FITC/CD4-RD1/CD3-PC5 • CYTO-STAT / COULTER CLONE CD3(IgG1)-FITC/T4-RD1 • CYTO-STAT / COULTER CLONE CD3(IgG1)-FITC/T8-RD1 • CYTO-STAT CD3-FITC/CD56-RD1 • CYTO-STAT / COULTER CLONE T4-RD1/T8-FITC • CYTO-STAT / COULTER CLONE T8-FITC (CD8-FITC) • CYTO-STAT / COULTER CLONE T8-RD1 (CD8-

Attribute	Q-Prep (Predicate)	TQ-Prep
		RD1) • CYTO-STAT / COULTER CLONE T4-FITC (CD4-FITC) • CYTO-STAT / COULTER CLONE T4-RD1 (CD4-RD1) • CYTO-STAT / COULTER CLONE CD3(IgG1)-FITC • CYTO-STAT / COULTER CLONE CD3(IgG1)-RD1
Device Classification and Product Code	862.2750, Pipetting and diluting system for clinical use, JQW	862.2750, Pipetting and diluting system for clinical use, PER
Manufacturer	Beckman Coulter, Inc.	Same
Controlling software	The timing electronics are on a single circuit board. They control the syringe delivery order, individual syringe priming cycles, continuous mix cycle, cycle reagent addition and mixing, and stop cycle.	The system microprocessor (386) assembly controls the touch screen, disk drive, power indicator, beeping device, and an internal communication link to the Control Interface card. A microcontroller, located on the Control Interface card, controls the motors, sensors, syringes, the cover/lid interlock switches, reagent level sense probes and an internal communication link to the system microprocessor assembly.

Attribute	Q-Prep (Predicate)	TQ-Prep
Lyse Reagents	ImmunoPrep A: Erythrocyte Lysing Reagent ImmunoPrep B: Stabilizing Reagent ImmunoPrep C: Cell Membrane Fixative	Same
Lyse Reagent Volume Range	ImmunoPrep A: 0.600 mL ± 5 % ImmunoPrep B: 0.265 mL ± 5 % ImmunoPrep C: 0.100 mL ± 5 %	Same
Timing	Premix: 2 ± 1 sec Lysing: 8 ± 1 sec Stabilizing: 10 ± 1 sec Fixative: 10 ± 1 sec	Same
Syringe Type	CAM-driven displacement syringes	Stepper Motor Tri-Continent Syringes
Mixing	• The mixer has a rotating arm that turns the bottom of the 12 x 75 mm test tube while a clip holds the top of the test tube in a fixed position. A circular rubber grommet holds the test tube in the arm. • The arm rotates at a rate of 1400 to 1800 rpm.	• The tube lifter/vortex mixer uniformly first lifts the tube up into the dispensing head, then mixes reagents in the sample. • The mixer rotates at 1400-1800 rpm.
Sample Introduction	Manual presentation into a tube location on front of instrument via tube access door. Single 12 x 75 mm tube only.	Automated presentation to sample processing area with Multi-tube Carousel Loader (MCL) from 32 test tube (12 x 75 mm) capacity carousel
Sample Identification	Manual, controlled by operator.	Same
Quality Control Techniques	Gravimetric calibration	Same

Similarities and Differences between Manual Pipette and PrepPlus 2 Workstation

Attribute	Manual Pipette (Predicate)	PrepPlus 2
Intended Use	Delivery of a specified volume of liquid. • In the tetraCHROME reagent application, it delivers whole blood, ImmunoTrol and ImmunoTrol Low Cells, tetraCHROME reagents, and Flow-Count Fluorospheres.	Intended Use: The COULTER PrepPlus 2, when used in combinations with the COULTER TQ-Prep Workstation, is intended to prepare human whole blood for In Vitro Diagnostic (IVD) Use with cleared Beckman Coulter IVD applications on cleared Beckman Coulter flow cytometers (see list below). Indications for Use: Pipetting blood, cleared Beckman Coulter IVD reagents and Flow-Count Fluorospheres to prepare samples for flow cytometric analysis. Use of the PrepPlus 2 with cleared Beckman Coulter flow cytometers is described in each application Instructions for Use. For In Vitro Diagnostic Use Only **IVD Applications** The following cleared Beckman Coulter IVD applications can be used with the TQ-Prep and PrepPlus2 Workstations on cleared Beckman Coulter flow cytometers as described in each application's Instructions for Use. • CYTO-STAT tetraCHROME CD45-FITC/CD4-RD1/

Attribute	Manual Pipette (Predicate)	PrepPlus 2
		CD8-ECD/CD3-PC5 • CYTO-STAT tetraCHROME CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 • CYTO-STAT triCHROME CD45-FITC/CD4-RD1/CD3-PC5 • CYTO-STAT triCHROME CD45-FITC/CD8-RD1/CD3-PC5 • CYTO-STAT triCHROME CD45-FITC/CD56-RD1/CD3-PC5 • CYTO-STAT triCHROME CD45-FITC/CD19-RD1/CD3-PC5 • CYTO-STAT triCHROME CD8-FITC/CD4-RD1/CD3-PC5 • CYTO-STAT / COULTER CLONE CD3(IgG1)-FITC/T4-RD1 • CYTO-STAT / COULTER CLONE CD3(IgG1)-FITC/T8-RD1 • CYTO-STAT CD3-FITC/CD56-RD1 • CYTO-STAT / COULTER CLONE T4-RD1/T8-FITC • CYTO-STAT / COULTER CLONE T8-FITC (CD8-FITC) • CYTO-STAT / COULTER CLONE T8-RD1 (CD8-RD1) • CYTO-STAT / COULTER CLONE T4-FITC (CD4-FITC) • CYTO-STAT / COULTER CLONE T4-RD1 (CD4-

Attribute	Manual Pipette (Predicate)	PrepPlus 2
		RD1) • CYTO-STAT / COULTER CLONE CD3(IgG1)-FITC • CYTO-STAT / COULTER CLONE CD3(IgG1)-RD1
Device Classification and Product Code	Not applicable	862.2750, Pipetting and diluting system for clinical use, PER
Manufacturer	Various	Beckman Coulter, Inc. is the manufacturer of record.
Controlling software	None	• Operating System – Loaded into the COULTER TQ-Prep Workstation. The user runs both the PrepPlus 2 and the TQ-Prep Workstation from the TQ-Prep Workstation touch screen commands. • Panel Definition software – This software allows the definition of panels, reagent racks, and control/calibrator racks. Standalone Panel Definition software also available.
Sample Identification	Manual, controlled by operator.	Same
Sample Introduction	Manual presentation.	Automated presentation with Multi-tube Carousel Loader (MCL) from 32 test tube (12 x 75 mm) capacity carousel
Sample Contact Material	Polypropylene disposable tip	Teflon-coated sample probe
Cleaning Cycle Between Samples	Pipette tip replaced between samples	Executed with IsoFlow Sheath Fluid in wash station after each liquid-handling function. Once daily COULTER CLENZ cleaning agent cleans and rinses the sample probe to prevent protein build-up.

Attribute	Manual Pipette (Predicate)	PrepPlus 2
Volume Range	Manual, controlled by operator.	5 µL to 1,000 µL. (Volumes over 500 µL are delivered in multiple aliquots. Maximum aliquot volume is 500 µL.)
Syringe Size	Not applicable	1.0 mL.
Specimen Tube Size	Variable	Based on the specimen tube's diameter: o 13-mm specimen cassette With Adaptor: o 75 mm specimen tubes o 2 mL specimen tubes (with 2 mL tube adaptor) o 3 mL specimen tubes (with 3 mL tube adaptor) o IMMUNO-TROL control tubes
Specimen Cassette Sizes	Not applicable	12 specimens per cassette for 13-mm specimen tubes
Prepared Sample Tubes (Daughter Tubes)	12 x 75 mm straight polypropylene test tube, round bottom.	Same

8.0 **Summary of Performance Data:**

Study	Study Design	Study Results
Accuracy	Based on CLSI EP09-A2, Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline--Second Edition (Interim Revision)	The TQ-Prep demonstrated comparable results to the predicate device with CYTO-STAT tetraCHROME Reagents (CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 and CD45-FITC/CD56-RD1/CD19/ECD/CD3-PC5).
Accuracy	Based on CLSI EP09-A2, Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline--Second Edition (Interim Revision)	The PrepPlus2 demonstrated comparable results to the predicate device with CYTO-STAT tetraCHROME Reagents (CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 and CD45-FITC/CD56-RD1/CD19/ECD/CD3-PC5).
Precision	Based on CLSI EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition.	The TQ-Prep and PrepPlus 2 demonstrated acceptable results with CYTO-STAT tetraCHROME Reagents.
Gravimetrics	Evaluate accuracy and precision of dispensing ImmunoPrep reagents.	The TQ-Prep demonstrated acceptable accuracy and precision results for dispensing ImmunoPrep reagents.
Gravimetrics	Evaluate accuracy and precision of dispensing blood, reagents, controls, and Flow-Count Fluorospheres.	The PrepPlus2 demonstrated acceptable accuracy and precision results for delivering blood, reagents, controls, and Flow-Count Fluorospheres.
Carryover	Based on CLSI Document: H26-A2, Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Approved Standard – Second Edition, Section 5.7: Carryover	The complete systems, composed of the TQ-Prep, PrepPlus 2, and FC 500 with tetraCXP software, for specimen and reagent demonstrated acceptable carryover performance.

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to products already in commercial distribution.

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 15, 2013

BECKMAN COULTER, INC.
C/O MS. NANCY NADLER
DIRECTOR, REGULATORY AFFAIRS
11800 S.W. 147 AVENUE
M/S 31-B06
MIAMI FL 33196-2500

Re: k130253
Trade/Device Name: COULTER TQ-Prep Workstation
COULTER PrepPlus2
Regulation Number: 21 CFR 862.2750
Regulation Name: Pipetting and diluting system for clinical use
Regulatory Class: I
Product Code: PER
Dated: July 05, 2013
Received: July 08, 2013

Dear Ms. Nadler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Maria M. Chan -S

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130253

Device Name: COULTER® TQ-Prep Workstation

Indications For Use:

Intended Use:
The COULTER TQ-Prep Workstation is intended to prepare leukocytes from whole blood for In Vitro Diagnostic (IVD) Use when used with the COULTER ImmunoPrep Reagent System and cleared Beckman Coulter IVD applications on cleared Beckman Coulter flow cytometers.

Indication for Use:
Pipetting of ImmunoPrep Reagent System (lyse, stabilizer, and fixative reagents) to samples prepared either manually or with the COULTER PrepPlus 2 sample preparation device to achieve lysis of whole blood samples. Use of COULTER TQ-Prep with cleared Beckman Coulter flow cytometers is described in each application's Instructions for Use. For In Vitro Diagnostic Use Only

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Maria M. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k): k130253

Indications for Use

510(k) Number (if known): K130253

Device Name: COULTER® PrepPlus 2

Indications For Use:

Intended Use:
The COULTER PrepPlus 2, when used in combinations with the COULTER TQ-Prep Workstation, is intended to prepare human whole blood for In Vitro Diagnostic (IVD) Use with cleared Beckman Coulter IVD applications on cleared Beckman Coulter flow cytometers.

Indications for Use:
Pipetting blood, cleared Beckman Coulter IVD reagents and Flow-Count Fluorospheres to prepare samples for flow cytometric analysis. Use of the PrepPlus 2 with cleared Beckman Coulter flow cytometers is described in each application Instructions for Use.

For In Vitro Diagnostic Use Only

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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